UTERINE ARTERY EMBOLISATION IN MANAGEMENT OF SYMPTOMATIC UTERINE FIBROID

Dissertation submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

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INSTITUTE OF OBSTETRICS AND GYNAECOLOGY
MADRAS MEDICAL COLLEGE
CHENNAI – 600 003.

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CERTIFICATE

This is to certify that the dissertation titled **UTERINE ARTERY EMBOLISATION IN MANAGEMENT OF SYMPTOMATIC UTERINE FIBROID** submitted by **DR.E.PRINCEY RAJAKUMARI** to the faculty of Obstetrics and Gynaecology, The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the requirement for the award of M.D. Degree (Obstetrics and Gynaecology) is a bonafide research work carried out by her under our direct supervision and guidance.

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ETHICAL COMMITTEE CERTIFICATE

I, **Dr.E.Princey Rajakumari** apply for the ethical committee certificate for the project **"Uterine artery embolisation for the management of symptomatic uterine fibroid"** under the guidance of **Prof Dr.Geetha Prasath MDDGO** , Institute of Obstetrics and Gynaecology, Egmore, Chennai-8.

I understand the implications of doing research with human subjects and will fully comply with the regulations and keep the dignity and protect the health of subjects at all costs.

Princey Rajakumari

Signature of Postgraduate student

I have no objection to guide this postgraduate student in the project mentioned above. I shall supervise that all the human rights are protected and research is carried on with the utmost humanitarian principles.

Geethaprasad

Signature of the guide **Seal of guide**

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I certify that this project has been presented in front of the Ethical Committee, duly formatted in this institution and that all the members of the Ethical Committee have given permission to conduct this research.

Saranvats

Signature of Ethical Committee Chairman **Seal of Chairman**

Date: 21.12.2009

DECLARATION

I hereby declare that the study entitled **UTERINE ARTERY EMBOLISATION IN MANAGEMENT OF SYMPTOMATIC UTERINE FIBROID** was done by me in the Institute of Obstetrics and Gynaecology (IOG), Madras Medical College, Chennai-600 003, during the period of my PG study for MD Branch II Obstetrics and Gynaecology from 2009 – 2011.

This Dissertation to Dr. M.G.R. Medical University is in partial fulfillment of University regulations for the award of MD Degree in Obstetrics and Gynaecology.

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INTRODUCTION

INTRODUCTION

Fibroid (also called uterine leiomyoma, myoma, leiofibromyoma, fibroleiomyoma and fibroma) is a **benign tumour** that originates from the smooth muscles of myometrium and the accompanying connective tissue of the uterus. Fibroids are the most common benign tumour in females and typically found during the middle and later reproductive years seen in 40-50% of women older than 35 years[1]. It is estimated to occur in 40% of menstruating women older than 50 years. Symptoms caused by uterine fibroids are frequent indication for hysterectomy. Fibroids are often multiple. Most patients with uterine fibroids are asymptomatic[2].

Most common presenting symptoms of fibroids are:

- Abnormal uterine bleeding.
- Dysmenorrhoea.
- Pelvic pain, possibly resulting from intramural degeneration, torsion of pedunculated fibroid or uterine contractions.
- Pelvic pressure.
- Abdominal distension in case of large fibroid
- Genitourinary dysfunction, which may manifest as the following:

- Increased urinary frequency resulting from bladder compression.
- Acute urinary retention.
- Flank pain resulting from urethral compression and hydronephrosis.

- Infertility.
- Rarely, lower extremity edema, constipation, or intestinal obstruction.

According to the location fibroids are called Intramural fibroids, Subserosal fibroid (sometimes pedunculated), Sub mucosal fibroids and cervical fibroids. Intra mural fibroids are the most common type causing menorrhagia and dysmenorrhoea. These intra mural fibroids can be treated with uterine fibroid embolisation.

Various Medical and surgical therapies are used to treat fibroids. Medical therapy includes hypo estrogenic drugs, which causes temporary reduction in size and relief of symptoms. Surgical treatment includes myomectomy or hysterectomy. Uterine fibroid is one of the leading causes for hysterectomy today in India and worldwide.

Transcatheter embolisation of the uterine arteries for symptomatic fibroids has become an increasingly important alternative treatment. It is

highly effective and well tolerated by most patients. Most notably, uterine artery embolisation is minimally invasive associated with a short recovery period and is uterine sparing.

Estimated 13,000-14,000 UFE procedures are performed annually in U.S. (as of 2004). In India uterine fibroid embolization is less popular and done in very few centres. This study is to determine the benefits and effectiveness of uterine artery embolization in symptomatic uterine fibroid and use the same as an alternate primary treatment for uterine fibroids.

AIMS OF THE STUDY

AIM

The aim of this study is to analyse the effectiveness, technique, complication and outcome after uterine artery embolisation in patients with symptomatic uterine fibroid.

TREATMENT OPTIONS

FOR FIBROID

TREATMENT OPTIONS FOR FIBROID

The ideal treatment should be minimally invasive, cost-effective, efficacious and tolerable with minimal side effects and have a low incidence of fibroid recurrence. Treatment for symptomatic uterine fibroid can be conservative or definitive

Conservative approaches are preferred for those who want to conserve the uterus for further child bearing or menstrual function. Both medical and surgical approaches are available for conservative management

MEDICAL METHODS:

Various hypo-estrogenic agents are tried to reduce the size of fibroid and to reduce the symptoms. They have various side effects and their effects are short lasting. E.g.: Ocps, Progestin, GnRH analogue, etc.

- **Oral contraceptive pills**[3] often are used to control menorrhagia and dysmenorrhoea. A drawback of this treatment is that the fibroids may increase slightly in size. For some women, the benefits of hormonal contraception outweigh the risk of side effects like weight gain, thromboembolism, etc. Hence OCP's rarely used in patients with fibroids.

- **Gonadotropin–releasing hormone** (GnRH) [4] agonists. These drugs reduce menorrhagia and can shrink fibroids. They sometimes are used pre-operatively to reduce the risk of bleeding. GnRH agonists have many side effects, including osteoporosis, vaginal dryness, and night sweats. For these reasons, they are used only for short periods (less than 6 months). Fibroids usually return to their previous size on stopping the treatment.
- Progestin– **Levonorgestrel releasing intrauterine device**[5] is an option for women with fibroids that do not distort the endometrial cavity. It reduces menorrhagia and dysmenorrhoea but does not treat the fibroids. LNG intrauterine devices can be used for 5years.
- **RU-486 (mifepristone)** 5-10 mg per day[6] used upto 6 months has also been shown to reduce fibroid size by half. This drug can also be used to reduce pelvic pain, bladder pressure and low back pain. Low doses of Mifepristone may reduce the size of fibroids in preparation for surgery to remove them. It may also help some patients avoid surgery entirely by shrinking the fibroids and the problems they are causing. Side effects related to low oestrogen, seen with GnRH analogs, may be less common. RU-486 can

induce miscarriage, it should be used with caution if a woman is trying to conceive.

- **Danazol**[4] has been used to reduce Menorrhagia in women with fibroids, but it does not shrink the size of fibroids. Danazol is androgenic that can cause serious side effects including weight gain, muscle cramps, decreased breast size, hirsutism, mood changes, depression, acne, decreased high density lipoprotein levels and increased liver enzyme levels.
- The selective progesterone receptor modulator **asoprisnil**[7] (10 and 25 mg daily for 3 months) are given to women with symptomatic fibroids who are scheduled for hysterectomy. Asoprisnil reduces uterine blood flow (determined by resistance index and pulsatility index) and volume of the largest fibroid and the uterus. Analysis of menstrual pictogram scores showed a significant decrease in frequency and intensity of bleeding compared with placebo. Further studies are required to evaluate safety and efficacy of asoprisnil when administered for long period.

CONSERVATIVE SURGICAL TREATMENT:

- **Myomectomy:**

Myomectomy[8] (abdominal/ laparoscopic) traditionally has been done to improve infertility in women who has uterine fibroids. Over the past ten years it has been utilized more routinely as a treatment for any women with fibroids who wish to conceive. Myomectomy may be done in a number of ways:

- Laparotomy
- Laparoscopy
- Hysteroscopy

Hysteroscopy[9] can be used to remove submucous fibroids that protrude into the endometrial cavity. A *resectoscope* is inserted through the hysteroscope. The resectoscope destroys fibroids with electrocautery or a laser beam. Although it cannot remove intramural and subserous fibroids, it often can control the bleeding. In most cases, an overnight stay in the hospital is only necessary.

- **Endometrial Ablation**:

Endometrial ablation can be accomplished by either using a hysteroscope dissect and cauterize the endometrium or by applying heat to the Endometrium. This cannot be used in patient who wants further pregnancy.

- **Myolysis**[10]:

There are two surgical methods which share the common concept of destroying the fibroids in uterus without necessarily removing them.

- **Myomacoagulation[10]:**

This approach is best used either alone or in combination with laparoscopic myomectomy when multiple tumours are encountered. In this technique myoma tissue is destroyed by Nd: YAG laser or bipolar cautery. It helps avoid tedious laparoscopic removal of multiple fibroids.Combination of myolysis and endometrial ablation may reduce the need for subsequent procedures in patients with persistent bleeding.

- **Cryomyolysis**:

This procedure uses a probe which freezes the tumour, causing death and shrinkage of the tumour. Cryomyolysis has not been broadly used, mostly because the instrumentation is very expensive

- ***Magnetic Resonance Imaging–Guided Ultrasound Surgery***[11].

In this new approach, ultrasound waves are used to destroy fibroids. The waves are directed at the fibroids through the skin with the help of magnetic resonance imaging. Studies show that women have improved

symptoms up to 1 year after having the procedure. Long-term efficacy is currently under study.

RADICAL TREATMENT:

- **Hysterectomy**:

Hysterectomy either abdominal or laparoscopic is the most radical surgical procedure for the treatment of uterine fibroids. It involves the removal of the uterus from pelvis, with preservation of the ovaries. Some of the complications that are associated with hysterectomy are the loss of support of the pelvic floor, risk involving regional or general anaesthesia, blood loss which may need blood transfusions. Damage to the Bladder, Bowels and ureter are possible and involves additional morbidity and mortality. It needs long post operative stay at hospital.

- **Uterine Artery Embolisation**:

UAE for the fibroid uterus was first used in 1995[12]. Since then it has be evolving as the primary treatment for fibroid. It is safe, simple, short hospital stay with less complication with high efficacy. Ischemia of uterine fibroids may also be achieved by a variety of techniques. Laparoscopic uterine artery occlusion[13] has been shown to yield equivalent results to UFE in the short term utilizing bipolar coagulation

or clips. Another procedure of temporary bilateral uterine occlusion performed with intravaginal,[14] "incision less" application of paracervical clamp with integrated audible Doppler ultrasound to treat uterine fibroids has been reported which is under study.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Embolization[15] is defined as the "therapeutic introduction of various substances into the circulation to occlude selective vessels, either to arrest or prevent haemorrhage, to devitalize a structure, tumour or organ."

Drs.Lussenhop and **Spence**[15] first occluded a cerebral arteriovenous malformation under radiographic and catheter guidance in 1960. **Charles Dotter** is acknowledged as founder of the specialty from his landmark work on angioplasty, first published in circulation in 1960. Another who contributed early was **Dr. Baum**, who developed techniques for controlling G-I bleeding using Vasopressin.

Following Drs.Lussenhops and Doppman in the USA, Japanese physicians developed selective catheter techniques for treating spinal cord AVMs. In 1972, **Dr. Dotter and Dr. Rosch**[15] again developed techniques for controlling bleeding due to ulcer disease by embolizing autologous clots. **Dr. White** et. al[15]. first used this technique successfully in 1974 to actually control ulcer bleeding with the survival of patient survived. Early in the 1970s, many radiologists began to use embolotherapy for lifesaving haemorrhages.

Since 1960's, embolization of uterine artery has been used to treat post partum haemorrhage. Uterine artery embolisation was used to control heavy bleeding from cervical carcinoma. A recent case report from Ottawa hospital,

Canada[16] says that uterine artery embolisation was used to control bleeding from cervical pregnancy. The embolic agents used are polyvinyl alcohol , acryilic spheres, gelfoam ,steel coils and these are approved by the U.S. Food and Drug Administration (FDA) for this purpose.

Uterine Artery Embolization for fibroid uterus was first used as a technique to limit blood loss during surgical removal of fibroids, and performed well before the surgery. However, it was found that after embolization and while awaiting surgery many patients no longer had symptoms and frequently the operation itself proved to be unnecessary. UAE was introduced as a treatment for fibroids in 1992 in Paris by **Dr. Jacques-Henri Ravina**[12], a gynaecologist. The treatment was first performed in the U.S. at the University of California at Los Angeles (UCLA). There are now many such centres on the world performing UAE to treat uterine fibroids.

Mahmood et al [17] (2002) from Department of Vascular and Interventional Radiology, Stanford University analyzed the outcomes of 111 consecutive patients who underwent abdominal myomectomy (n = 44) or fibroid embolization (n = 67) over a 30-month period. The respective observed success rates in abdominal myomectomy and uterine fibroid embolization patients were 64% versus 92% for menorrhagia ($p < 0.05$), 54% versus 74% for pain (not significant), and 91% versus 76% for mass effect ($p < 0.05$). The complication rates were 25% (abdominal

myomectomy) and 11% (uterine fibroid embolization)($p < 0.05$). The respective secondary end points for the two procedures were 2.9 versus 0 days mean hospital stay, 8.7 versus 5.1 days of narcotics use, and 36 versus 8 days until resumption of normal activities. These differences were all statistically significant. He concluded that uterine fibroid embolization was a less invasive and safer treatment option in women with symptomatic leiomyomas than myomectomy. Menorrhagia may be better controlled with embolization [and] myomectomy may be a better option in patients with mass effect. Both procedures were equally effective in controlling pain.

Spies[18] (1999) from Georgetown University Medical Centre presented results of 61 patients who underwent uterine fibroid embolization. During a 16-month period menstrual bleeding was improved in 89%, with 81% of patients moderately to marked improvement. Pelvic pain and pressure was improved in 96% of patients, with moderate to marked improvement in 79%. At initial imaging follow-up (mean, 4.4 months post procedure), median uterine volume decreased 34% ($P = .0001$) and the median dominant fibroid volume decreased 50% ($P = .0001$). Imaging at 1 year (mean, 12.3 months) after the procedure showed continued reduction with a median uterine volume reduction of 48% ($P = .0002$) and median dominant fibroid volume decrease of 78% ($P = .0002$). The authors concluded that UFE appears effective in controlling symptoms and substantially reducing fibroid volume with few complications.

Pron et al [19] (2003) reported on the Ontario Uterine Fibroid Embolization Trial, which enrolled 555 women. The median follow-up was 8.9 months. Menorrhagia improved in 83% of women following the procedure, dysmenorrhea improved in 77% and urinary frequency improved in 86% of women. The mean fibroid volume reduction for the dominant fibroid was 33% at 3 months. Amenorrhea occurred in 8% of women. The complication-related hysterectomy rate in the Ontario UFE Trial was 1.5% within 3 months of the embolization.12 of the 8 procedures, 2 were for infection, 4 for persistent post embolization pain, 1 for a 10 cm prolapsed leiomyoma, and 1 for persistent vaginal bleeding.

Spies J, **et al** [20] (2004) done a multicenter control trail comparing the Outcome of Uterine Embolization and Hysterectomy for Leiomyomas. Study published in American Journal of Obstetrics & Gynaecology. Spies J, et al states that shorter hospital stay with UFE: < one day versus Hysterectomy 2.3 days. Return to work UFE: 10.7 days versus Hysterectomy: 32.5 days and Fewer complications (after 30 days) UFE: 12.7% versus Hysterectomy: 32%

Jain et al [21] (2004) from All India Institute of Medical Sciences, New Delhi carried out a study determines the effectiveness of uterine artery embolization (UAE) as a primary treatment of symptomatic fibroids. Study was carried out in total of 32 patients aged 25–49 years (mean 40.9 years). Procedure was carried out through unilateral femoral puncture using poly vinyl

alcohol (PVA) particles 355–500 μm in size. All 32 patients had successful procedures. Overall, 25 patients responded, giving a clinical success rate of 78.12%. Mean reduction in volume of fibroid was 59.7% (range 31.6–83.3%) and 75.5 %(range 46.2–96.8%) on USG at 3 and 12 months. He concluded that uterine artery embolization leads to good technical success and fibroid volume reduction.

Tranquart et al [22] (2005) from France evaluated the sonographic feature of 58 women following uterine artery embolization and to assess the efficacy of embolization as the primary treatment of fibroids. Most patients were improved or free of symptoms at 3 months (90%), 6 months (92%) and 1 year (87%) and all monitored patients were free of symptoms at 2 years. Clinical failure of treatment occurred in only two cases (3%). Progressive significant reduction in fibroid size with reference to the baseline was demonstrated during follow-up from 3 months (29%) to 24 months (86%). He concluded that uterine artery embolization was a valuable endovascular method for the treatment of fibroids, resulting in marked reduction in fibroid size and disappearance of intrafibroid vessels without reduction in uterine vascularisation

Albert. J. Smeets et al [23] (2009) from Department of Radiology of St. Elisabeth Ziekenhuis in Netherlands evaluated the controversial issues of Uterine artery embolization (UAE) in patients with a large fibroid burden .Seventy-one consecutive patients (mean age, 42.5 years; median, 40 years;

range, 25–52 years) with a large fibroid burden were treated by UAE between August 2000 and April 2005. There were no serious complications of UAE. During a mean follow-up of 48 months (median, 59 months; range, 6–106 months), 10 of 71 patients (14%) had a hysterectomy. Mean volume reduction of the fibroid and uterus was 44 and 43%. Mean infarction rate of the fibroid and overall fibroid infarction rate was 86 and 87%. In the vast majority of patients there was a substantial improvement of symptoms. Clinical results were similar in patients with a dominant fibroid >10 cm and in patients with large uterine volumes by diffuse fibroid disease. Their results indicate that the risk of serious complications after UAE in patients with a large fibroid burden was not increased. Moreover clinical long-term results are as good as in other patients who are treated with UAE. Therefore a large fibroid burden should not be considered a contraindication for UAE.

In another article on Uterine Fibroid Embolization **Goodwin**[24] and **Spies** highlight few contraindications to the procedure like pregnancy, suspected cancer, active infection indeterminate endometrial or adnexal abnormalities. They also cite the U.K. Hysterectomy or Percutaneous Embolisation for Uterine Leiomyomata **(HOPEFUL)**[25] study, which showed 2.6% incidence of septicaemia after uterine fibroid embolization, with 1.1% of the women requiring emergency hysterectomy. Severe infection, often necessitating urgent

hysterectomy, was a rare but well-established complication of uterine fibroid embolization.

The Fibroid registry[26] (Fibroid Registry for Outcomes Data) of 3160 patients showed an emergency hysterectomy rate of only 0.09% at 30 days. Emergency hysterectomy for bleeding has been described 4 months after uterine fibroid embolization.

In the Randomized Clinical Embolization versus Hysterectomy (**EMMY**) [27] trial, researchers in The Netherlands found those six weeks after treatment, women who underwent UFE reported higher satisfaction scores than those who had hysterectomies. Two years later, 90 percent of the women in both categories said they were satisfied with their therapies, the researchers reported in the March 2008 edition of Radiology.

Ninety percent of women who underwent UFE avoided a hysterectomy, said **Scott Goodwin, M.D.**, [28] the lead author and a professor and chair of the Department of Radiological Sciences in the School of Medicine at the University of California, Irvine. Study results were published in the January 2008 issue of Obstetrics & Gynaecology.

Research at **Georgetown University** [29] till 1999, 20.000 to 25,000 patients has had this procedure world-wide. Their initial results, along with those that have been published or presented at scientific meetings,

says that symptomatic improvement in 85-90% of patients with the large majority of patients markedly improved. The improvement rate was similar for heavy menstrual bleeding and for pressure and pain symptoms. Most patients have rated this procedure as very tolerable and in almost all cases hospitalization is necessary for only one night. In some centres, the patients are treated and discharged the same day. The expected average reduction in the volume of the fibroids is 40-50% in three months, with reduction in the overall uterine volume of about 30-40%. Over time, the fibroids continue to shrink. With several years follow-up now available, it appear that fibroids are successfully treated does not re grow.

Giovanna Tropeano et al[30] from Department of Obstetrics and Gynaecology, University Catholic del Sacro Cuore, Italy reports 50–60% reduction in fibroid size and 85–95% relief of symptoms following UAE. UAE offered shorter hospital stays (1–2 days for UAE versus 5–5.8 days for hysterectomy) and recovery times (9.5–28 days for UAE versus 36.2–63 days for surgery) and major complication rates (2–15% for UAE versus 2.7–20% for surgery, in 3 Randomised control trials. Four studies analysing cost-effectiveness found UAE more cost-effective than surgery. There is insufficient evidence regarding fertility and pregnancy outcome after UAE. They concluded that good quality evidence supports the safety and effectiveness of UAE for women with

symptomatic fibroids. The current available data are insufficient to routinely offer UAE to women who wish to preserve or enhance their fertility.

Hayden Homer [31] Department of Obstetrics and Gynaecology, Institute for Women's Health, University College London has said that data on pregnancy following uterine artery embolisation (UAE) are scarce, with just over 200 pregnancies reported. Two small prospective trials of UAE versus surgical intervention suggest increased levels of adverse pregnancy outcomes following fibroid embolisation. This study suggests that in the absence of more robust evidence, caution should be exercised in recommending UAE to women who wants to retain their reproductive ambitions.

Joao and Marisa [32] (2010) studied on pregnancy out come after uterine fibroid embolisation. This study shows comparable fertility rates between the two primary uterus-sparing treatments uterine fibroid embolization (UFE) and surgical myomectomy, which is considered the gold standard for symptomatic fibroids in women who wish to conceive. Of the 743 patients who received UFE treatment, 74 wanted to conceive and had been unable. Most women opted for UFE as a fertility treatment after failure of myomectomy or in vitro fertilization or because hysterectomy was the only suggested option. Of the 74 women who wanted to become pregnant, 44 of

them became pregnant (59.5%). There are five (11.3%) ongoing pregnancies and 39 (88.7%) finished pregnancies, with 33 successful live births (84.6%), four spontaneous abortions (10.3%), one induced abortion and one stillbirth. There were 22 caesarean deliveries (66.6%), two preterm deliveries at 36 weeks (6.1%) and five low birth weights. This study concluded that in the future, UFE will probably be a first-line treatment option even for women who wish to conceive and are unable due to the presence of uterine fibroids.

Rashid. S. et al [33] studied the effects of Uterine Artery Embolisation and Surgical Treatment on Ovarian Function in Women with Uterine Fibroids. Some studies have shown that patients treated with UAE develop amenorrhea (with rates varying from 1%–8% and as high as 14%) and have increased follicle-stimulating hormone (FSH) levels (within the menopausal range) suggesting ovarian dysfunction may occur as a consequence of UAE. This study compares the effects of UAE and surgery on ovarian function and menstrual cycle characteristics in women with uterine fibroids. The impact of age on ovarian function was also studied. All surgical patients had ovarian conservation at the time of surgery. Ovarian function assessed by the levels of serum FSH were measured on day 3 of the menstrual cycle before treatment, and at 6 and 12 months post-treatment and menstrual cycle characteristics. No significant difference was found between the two treatment groups in the rate of ovarian failure at 12 months (UAE: 11% versus surgery: 18%; $P = 0.44$. These

findings provide no evidence that UAE accelerates deterioration in ovarian function at 1 year, in comparison with surgery.

Van der Kooij SM et al [34] (2010) from Department of Radiology, Academic Medical Center, Amsterdam compared the clinical outcome and health related quality of life (HRQOL), 5 years after uterine artery embolization (UAE) or hysterectomy in the treatment of menorrhagia caused by uterine fibroids. Patients with symptomatic uterine fibroids who were eligible for hysterectomy were assigned randomly 1:1 to hysterectomy or UAE. Endpoints after 5 years were re-intervention rates, menorrhagia and HRQOL measures that were assessed by validated questionnaires. UAE had a positive effect both on urinary and defecation function.

MATERIALS AND METHODS

MATERIALS AND METHOD

In this study 32 patients with fibroid uterus having at least one of the following symptoms are selected

1. Menorrhagia
2. Dysmenorrhoea
3. Pressure symptoms like
    - Lower abdominal heaviness
    - Increased frequency of micturation
    - Constipation

Patients were explained about the uterine fibroid embolisation, an alternate method to treat fibroid without hysterectomy. Patients were explained about the expected outcomes, side effects and risks involved like perforation of arteries, need for emergency laprotomy, possibility of treatment failure and need for future hysterectomy. They were also informed about alternative treatment options available. Written consent obtained from all patients who were ready to participate in the study. Those who accepted to undergo uterine fibroid embolisation were subjected to further investigations.

Patient Selection Criteria

- **Inclusion criteria**

1. Women with symptomatic fibroid (menstrual disturbances or pressure symptoms due to size or pain) who want to retain their uterus and avoid surgery.

2. Solitary or multiple intramural fibroids of less than 7 cm.

3. Parous women who completed family and age less than 40 yrs.

4. Women who give consent to undergo uterine artery embolisation and participate in study.

- **Exclusion criteria**

1. Women with asymptomatic fibroid.
2. Infertile women or parous women who want to conserve uterus for future pregnancy.
3. Fibroids of more than 7 cm or with degenerative changes or hypovascularity on Doppler study.
4. Sub mucous or pedunculated Subserosal fibroid.
5. Previous history of anaphylaxis to contrast.
6. Systematic illness like HIV, HbsAg +ve, abnormal renal profile, Coagulation disorders.

Study Design: Prospective interventional trial

Study Place: Institute of Obstetrics and Gynaecology, Chennai.

Collaborating Unit: Bernard Institute of Radiology, MMC

Study Population: Women with symptomatic fibroid

Sample Size: 30 Women with symptomatic fibroid.

METHODOLOGY:

A detailed history was taken to know the severity of symptoms. Menorrhagia was assessed by

Pictorial Blood Loss Assessment Chart (Hallberg et al.)[41]. Patients were asked to keep a detailed menstrual calendar denoting the number of pads used, soakage of each pad, duration of flow and passage of clots.

Pictoral blood loss scoring is given below

- Towels

1 point – For each lightly stained towel

5 points - For each moderately soiled towel

20 points - If the towel is completely saturated with blood

- Tampons

1 point - For each lightly stained tampon

5 points - For each moderately soiled tampon

20 points - If the tampon is completely saturated with blood

- Clots

1 point - For small clot

5 point - For large clot

5 point - For flooding

Pictorial Blood Loss Assessment Chart scoring was done before the treatment, 3 months and 6 months after treatment.

Dysmenorrhoea was assessed by

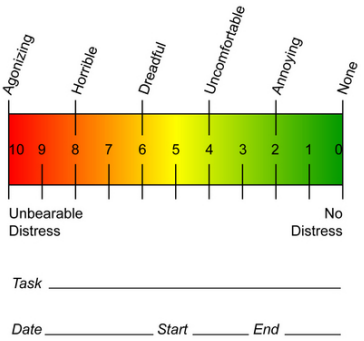
Visual analogue scale[42] using a 10-cm line represented the continuum.One extremity of the line represents ‘Unbearable pain’ and the other extremity represents ‘No pain at all’. The participants were asked to rate the degree of pain by making a mark on the line.

The scores received from the scale is classified into

1–3 points mild dysmenorrhea

4–7 points moderate dysmenorrhea

8–10 points severe dysmenorrhea



- Pressure symptoms were assessed by the presence or the absence of lower abdominal heaviness, increased frequency of micturation or constipation.

Investigations:

- Basic blood investigations done including Hb%, Blood urea, Serum creatinine, HIV, HbsAg, coagulation profile.
- Usg abdomen and pelvis done to know the location, size, number and volume of fibroid. Those who had degenerations (calcification or cystic degeneration) are excluded from the study.
- Doppler Usg done to know the vascularity of fibroid. Hypo vascular fibroids are excluded from study.
- Fractional curettage performed to rule out any associated malignant changes in endometrium.

Patients fit for UFE according to the inclusion criteria were taken up for UAE after adequate counselling. Eligible patients were advised to use contraception before the procedure and LMP confirmed.

PERFORMA: See annexure

PROCEDURE:

Pre Anaesthetics

- Inj Dexamethasone 8mg I.V Stat
- Inj. Pheniramine Maleate I amp I.M Stat
- Inj. Atropine Iamp I.V.Stat

Anti biotic prophylaxis:

- Inj Ampicillin 1gm I.V (ATD)

Anesthesia/ Sedation:

- Inj Tramadol 1 amp IM

Patient position: Supine

Approach: Percutaneous transfemoral approach

- With aseptic precautions under local anaesthesia femoral puncture was made.
- Internal iliac catheterized with single multipurpose 4F- 5F cobra catheter.
- Contra-lateral uterine artery was selectively catheterized
- Angiography and Embolisation was performed using an 800mA conventional angiographic unit (SIEMENS).
- Free flow embolisation was performed just beyond the junction of the horizontal and descending portions of the uterine arteries using

absorbable gelatine sponge shavings or poly vinyl alcohol as the embolic agent.

- Catheter withdrawn up to ipsi-lateral common iliac artery then passed into ipsi-lateral internal iliac and ipsi-lateral uterine artery. Embolisation done on the ipsi-lateral side.
- Stagnation of contrast medium was evidenced in the uterine capillary network at the end of embolisation, and an absence of flow was depicted in the uterine artery by injecting contrast medium into hypogastric arteries.

Endpoint of Embolisation

Occlusion of the identifiable vessels supplying the fibroids with preservation of normal uterine flow.

- Evidence of “standing column of contrast” in the uterine artery and reflux towards the uterine origin or into the internal iliac artery.
- Cessations of flow in the ascending uterine artery with residual flow in the lower uterine segments supplying the normal myometrium

Adverse Complications:

Nil/ Spasm/ Vessel dissection/ Vessel perforation/ Inadvertent embolisation/ Reflux of Embolic material into main artery/ Allergic reaction

Post procedure events:

Patients were observed in high dependence ward for 6 hrs then at least 48 hrs in the routine wards. All the patients were carefully observed for any complications like groin haematoma /retroperitoneal haematoma. Vitals were checked. Patients were kept nil per oral for 4 hours. They were advised bed rest for 6 hours and then ambulated. Patients were discharged after 48-72 hrs.

On discharge:

Patients were advised to report immediately if

- Any unbearable lower abdominal pain
- Fever or Purulent vaginal discharge
- Swelling in lower limbs
- Breathing difficulty

All of them were advised to maintain menstrual calendar in detail regarding the duration, number of pads soiled, clots passed and associated pain.

Follow up:

At the end of 3rd month patients were called and enquired about their menstruation, dysmenorrhoea and pressure symptom. USG Pelvis performed to know the size & volume of fibroid. Similarly at 6th month patients were called, enquired and a review USG was taken.

FIG5.1:CATHETERISATION OF UTERINE ARTERY

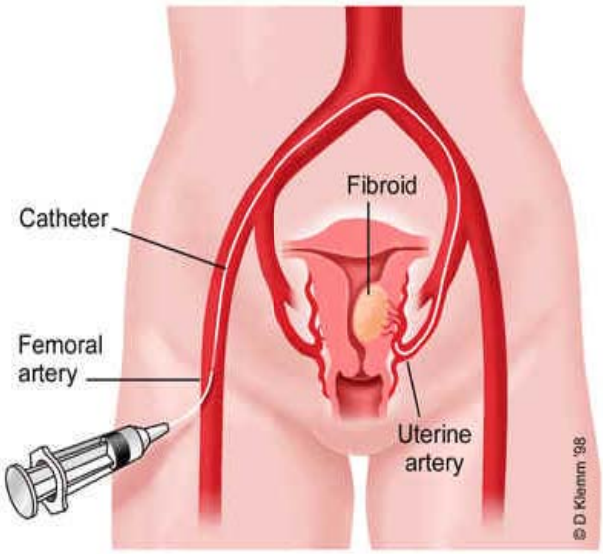


FIG5.2: CATHETER POSITION AND EMBOLISATION

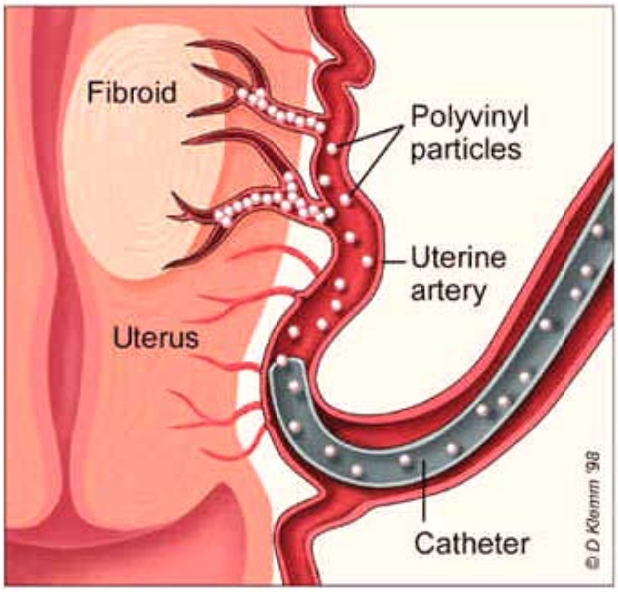


FIG 5.3: PUNCTURE NEEDLES

FIG 5.4: INTRODUCER SET

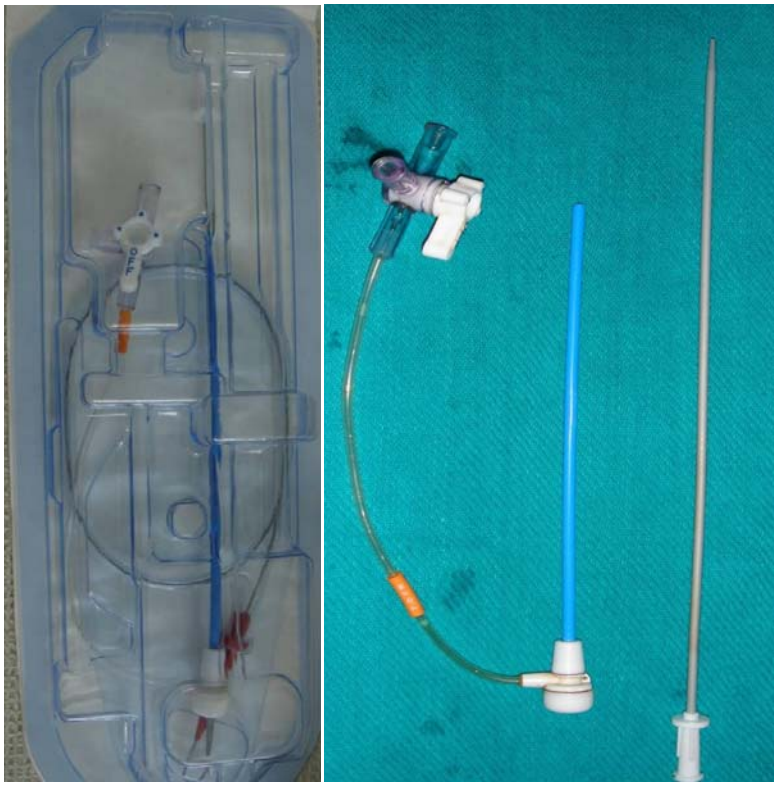
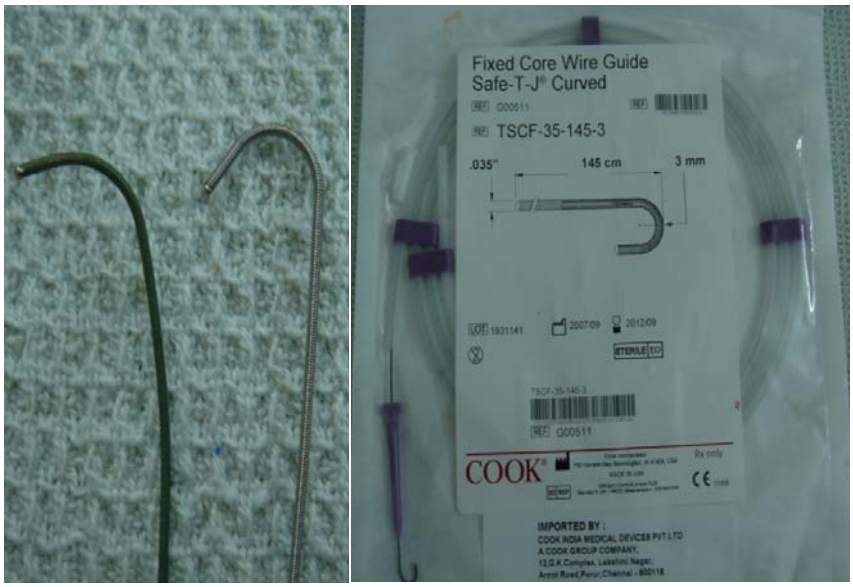


FIG 5.5: CATHETERS

FIG 5.6: GUIDE WIRES



EMBOLIC AGENTS

FIG 5.7: GELFOAM

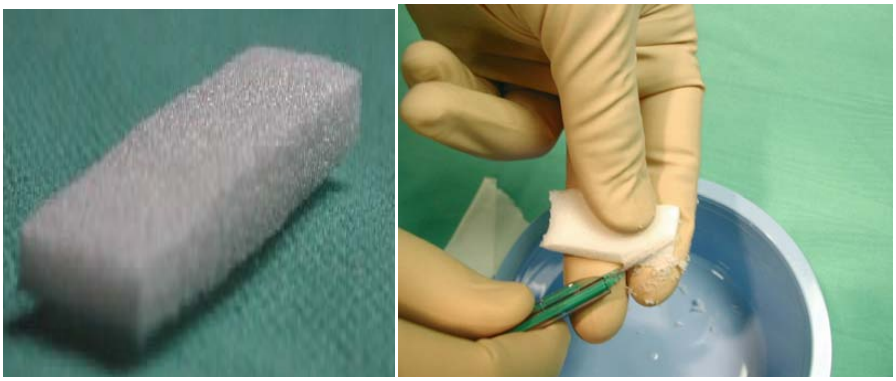


FIG5.8: POLY VINYL ALCOHOL PARTICLES


REF
PVA
200
COOK
REF
PVA
1000
COOK
REF
PVA
300
COOK
REF
PVA
500
COOK
REF
PVA
700
COOK
REF
PVA
2000
COOK

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ANALYSIS

ANALYSIS AND RESULTS

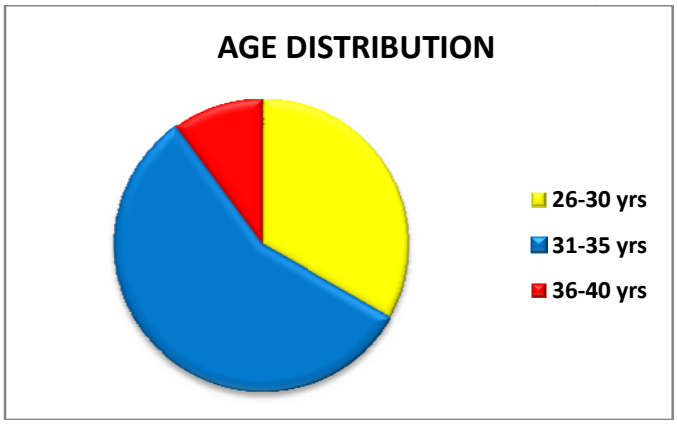
32 patients with uterine fibroid who were fit according to the inclusion criteria were taken up for the study. Embolisation was done after adequate counselling and getting informed written consent. Successful embolisation was done in 30 patients. Therefore data was analysed for 30 patients.

AGE

In this study women below the age of 40 yrs. are selected for UFE. Age distribution of the study population is given below.

Table: 1."Age Distribution Of Subjects"

Age Group	Frequency	%
26-30	10	33.33
31-35	17	56.67
36-40	03	10.00
Total	30	100.00



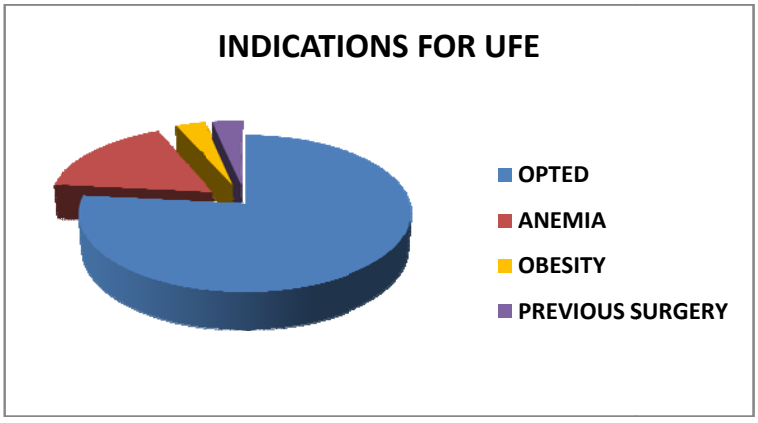
Mean age of the study population was 32.43 yrs and range was 26-39yrs.

INDICATION FOR EMBOLISATION:

Among 30 patients 23 (76.67%) patients preferred uterine artery embolisation than Hysterectomy. Out of 7 patients 5 (16.67%) were severely anaemic because of menorrhagia so preferred uterine artery embolisation for anaesthetic risks. One patient had undergone two laprotomies previously hence preferred uterine artery embolisation for her menorrhagia. One patient was morbidly obese. She preferred uterine artery embolisation considering the risk of thromboembolism, wound infection etc...

Table:2 "Indications- Distribution Of Subjects"

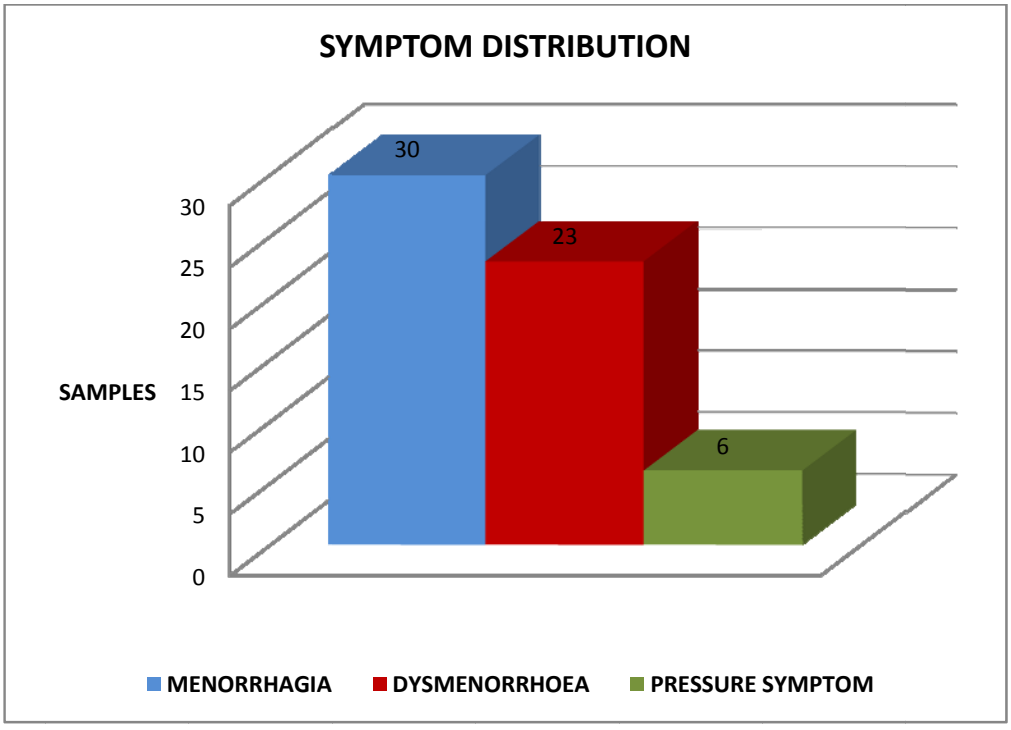
Indications	Frequency (No. Of Subjects)	%
Opted	23	76.67
Anaemia	05	16.67
Obesity	01	03.33
Previous Surgery	01	03.33
Total Subjects	30	100.00



PRESENTING COMPLAINTS:

Among menorrhagia, dysmenorrhoea and pressure symptoms, menorrhagia was the most common presenting symptom. It was present in all the patients. Dysmenorrhoea was present in 23 (76.66%) of the subjects. Pressure symptoms was present in 6 (20%) of the patients.

Table:3 "Symptoms- Distribution Of Subjects"		
Symptoms	Frequency	%
Menorrhagia	30	100.00
Dysmenorrhoea	23	76.66
Pressure Symptom	06	20.00

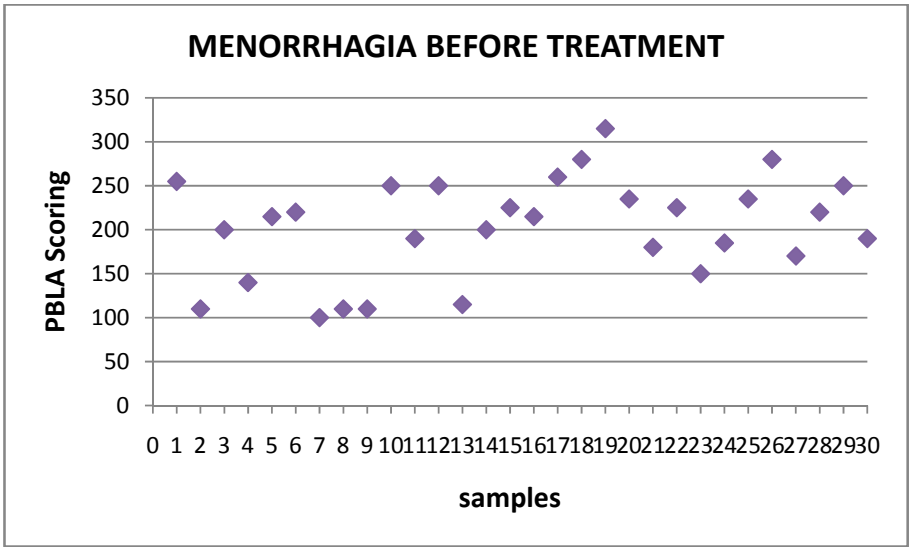


MENORRHAGIA:

Menorrhagia was present in all of the subjects. Menorrhagia was assessed by Pictoral Blood Loss Assessment Chart. As per **Higham et al**[43] who analysed pictoral blood loss, PBAC scoring of >100 is diagnostic of menorrhagia, that is blood loss of >80ml with specificity and sensitivity of >80. All patient had Pictoral blood loss assessment scoring of >100. Average blood loss scoring in this study was 202.66 and ranges from 100-315.Pictoral blood loss assessment scoring distribution of the patients before treatment is given below.

Table 4: "Menorrhagia distribution"

PBLA Scoring	Samples	%
100-150	7	23.33
151-200	7	23.33
201-250	11	36.66
>250	05	16.66
Total	30	100.00

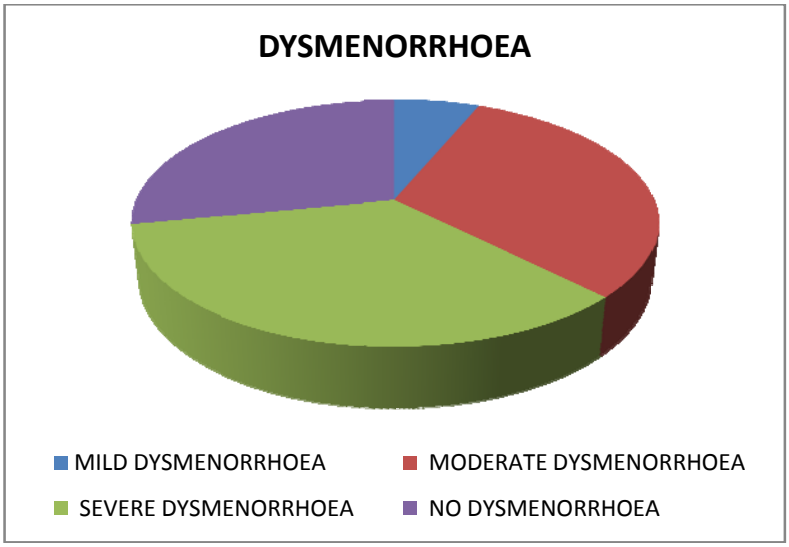


DYSMENORRHOEA

Dysmenorrhoea was assessed by visual analogue scale[42]. Before embolisation mild dysmenorrhoea was present in 2 patients, moderate dysmenorrhoea was present in 10 patients and severe dysmenorrhoea in 11 patients.

Table: 5. "Dysmenorrhoea Before Treatment"

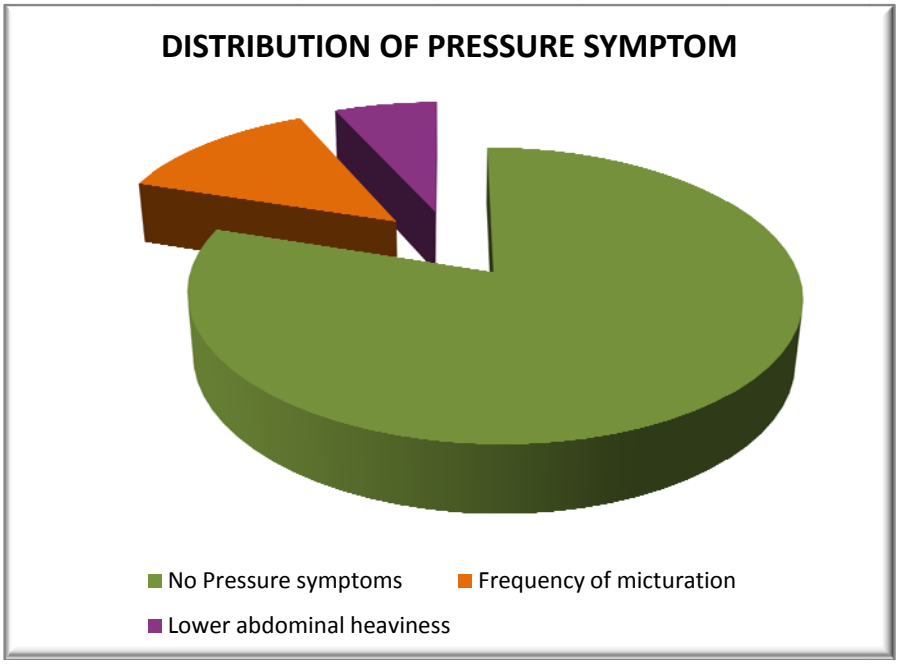
Grading	No of Subjects	%
No Dysmenorrhoea	07	23.33
Mild Dysmenorrhoea	02	06.67
Moderate Dysmenorrhoea	10	33.33
Severe Dysmenorrhoea	11	36.67
Total	30	100.00



PRESSURE SYMPTOMS:

Pressure symptoms present in 6 of the patients (20%).4 had increased frequency of micturation and 2 had feeling of lower abdominal heaviness.

Table:6"Distribution Of Pressure Symptom"		
Pressure symptoms	No of subjects	%
No Pressure symptoms	24	80.00
Frequency of micturation	04	13.33
Lower abdominal heaviness	02	06.67
Total	30	100.00

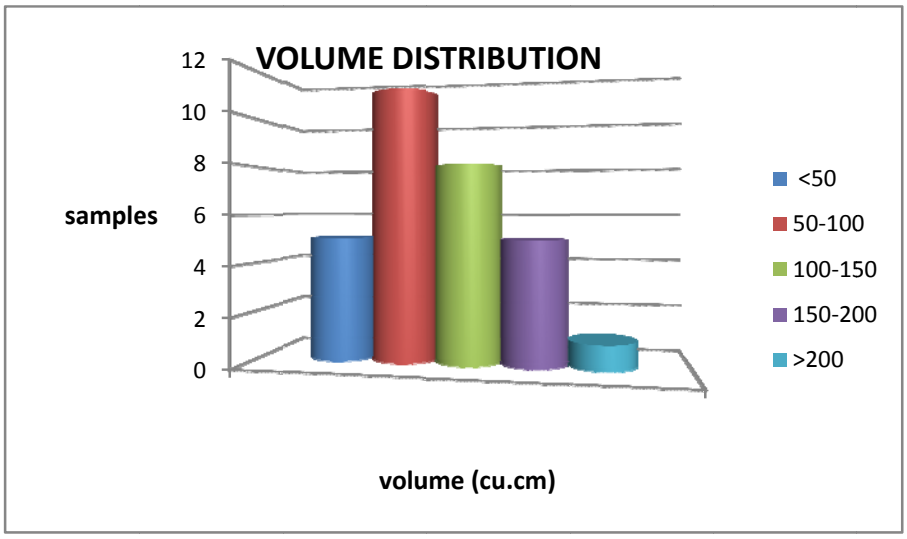


SIZE AND VOLUME:

Fibroid volumes are determined with the formula $A \times B \times C \times 0.523$, where *A*, *B*, and *C* are the dimensions in the three orientations in ultrasound assuming the fibroid has an ellipsoid shape[44] .Volume of fibroid in this study ranges from 40.01 - 276.14 cu cm. Average volume of fibroid before treatment was 104 cu cm. Largest size of fibroid in this study was 10x 8x6.6cm. Volume distribution of fibroid is given below.

Table:7. " Volume Distribution Of Fibroids "

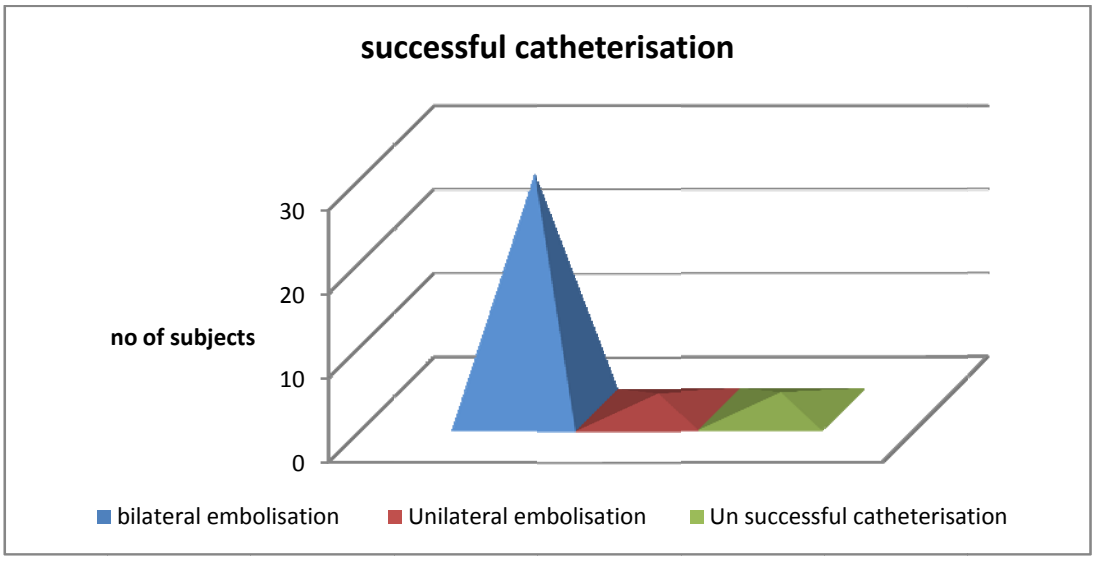
Volume of fibroid (cu cm)	No of subjects	%
<50	05	16.67
50-100	11	36.67
100-150	08	26.66
150-200	05	16.67
>200	01	03.33
Total	30	100.00



TECHNICAL DIFFICULTIES:

Technical difficulties was seen in 3 (9.99%) of the patients. Catheterisation of uterine artery was difficult because of vasospasm in 3 patients. Unilateral embolisation was done in one patient and other two patients catheterisation could not be done on both sides and the procedure abandoned. For another patient unilateral embolisation done because of sub intimal dissection on one side.

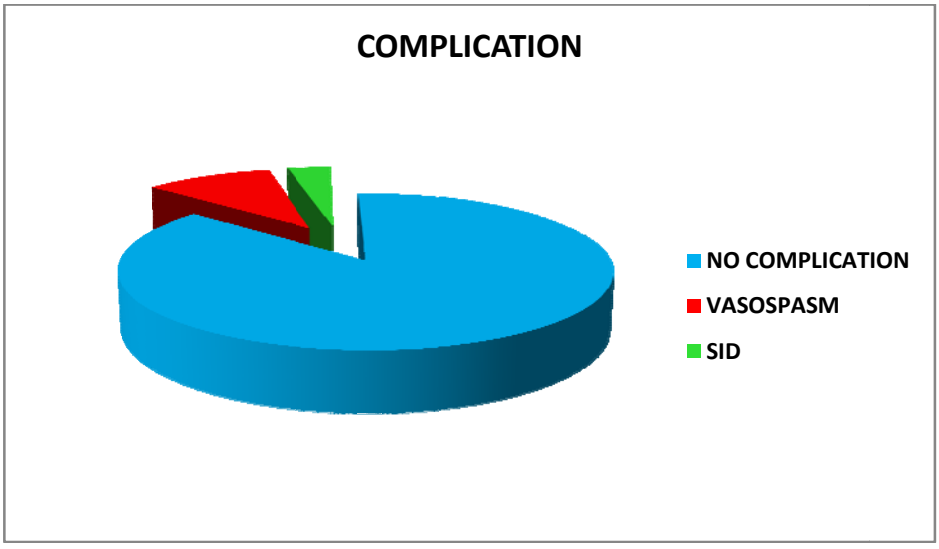
Table: 8. Technical Difficulties		
Technical difficulties	No of subjects	%
Bilateral embolisation	28	87.5
Unilateral embolisation	2	6.25
Unsuccessful catheterisation	2	6.25
Total	32	



COMPLICATIONS:

Complication rate in this study was 3.12% (serious complication). One case of sub-intimal dissection was seen. For her embolisation was successfully done in the contra lateral side. Then on catheterising the ipsi-lateral side sub-intimal dissection occurred and further procedure abandoned. Inj heparin 5000 u sc BD was started. No long term sequelae was seen in that patient. No other major complication occurred during the procedure. As explained earlier 3 patients had vasospasm.

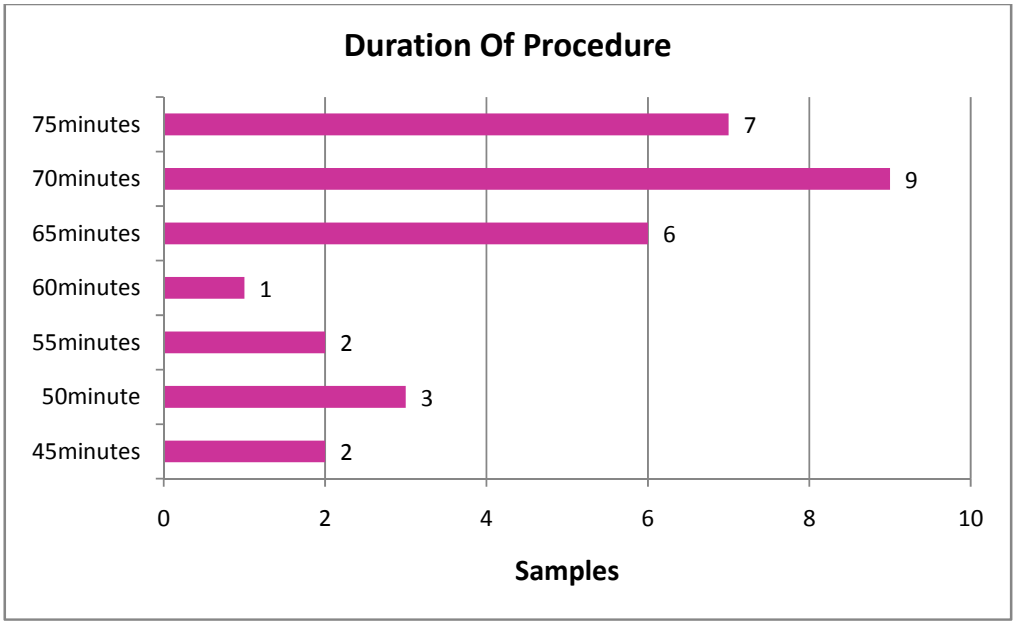
Table: 9. Complications During Procedure		
Category complication	No. Of Subjects	%
Vasospasm	03	09.38
Subintimal dissection	01	03.12
No Complication	28	87.50
Total	32	100.00



DURATION OF PROCEDURE:

In this study we have used unilateral catheterisation. Average total duration of the procedure [fluoroscopic exposure time] is 1hour 5minitue. Total duration varied from 45minute to 75 minute.

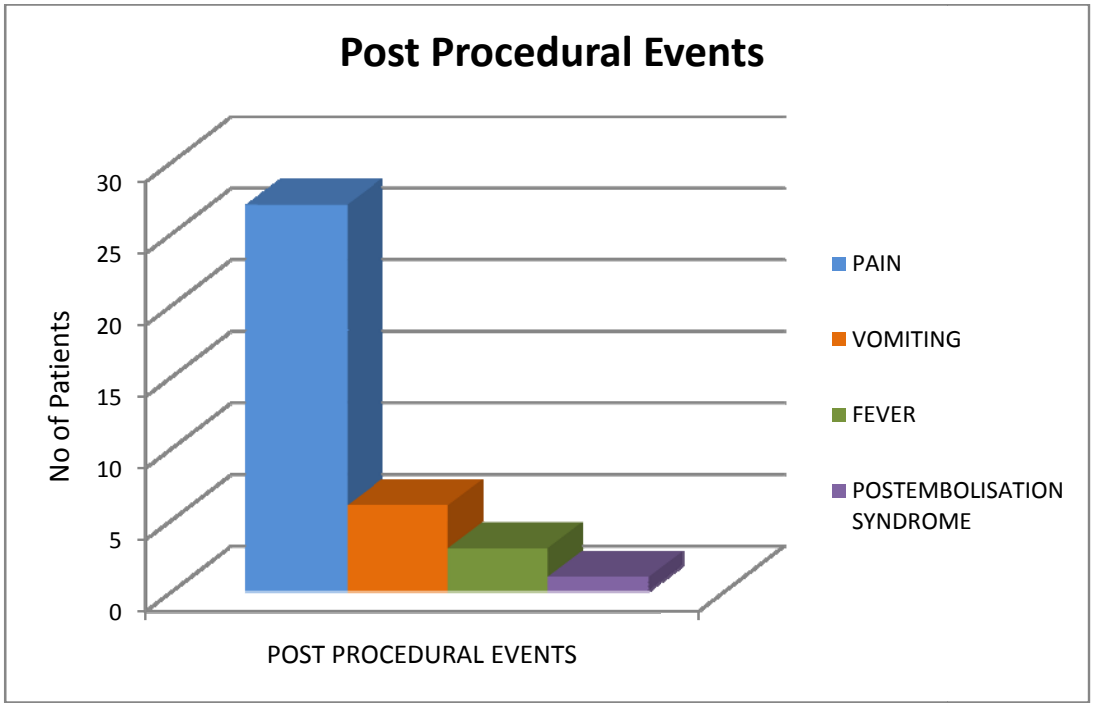
Table: 10. Duration of procedure	
Duration in minutes	No. Of Subjects
45	2
50	3
55	2
60	1
65	6
70	9
75	7
total	30



POST PROCEDURAL EVENTS:

90% of the patients complained of pain in the lower abdominal and low back ache.20% had vomiting and10% had fever. All these complications were self limiting. One patient had post embolisation syndrome (PES) and was re-admitted after a week.

Table: 11. Post Procedural Events		
Complication	No Of Patients	%
Pain	27	90
Vomiting	6	20
Fever	3	9.99
PES	1	3.33

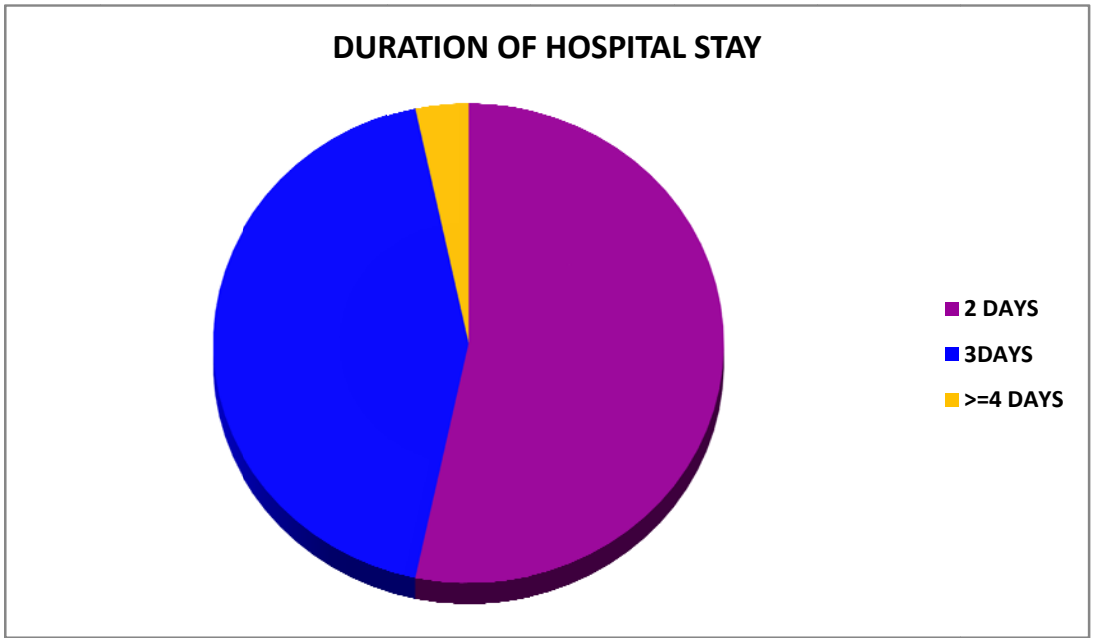


DURATION OF HOSPITAL STAY

Average duration of hospital stay for the patients who underwent UFE was 2.6 days. Range of duration of hospital stay was 3 to 7days. One patient who had sub intimal dissection stayed for 7 days. All other patients discharged on 2nd or 3rd day

.

Table: 12. Distribution Of Duration of Hospital Stay		
Duration	No Of Patients	%
2 Days	16	53.34
3days	13	43.33
>=4 Days	1	3.33



FOLLOW UP ANALYSIS:

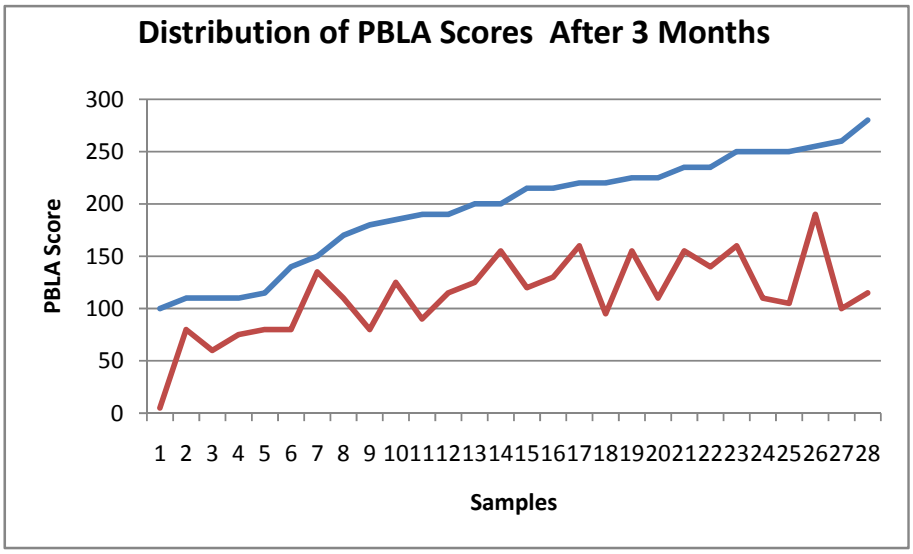
At the end of 3rd month all the 30 patients came for follow up. Their menstrual calendar was analysed, symptoms enquired and clinical examination was done. USG was done for all patients to assess the size and volume of the fibroid. Only 12 patients completed 6th month follow up. Others yet to come for follow up at 6 months.

MENORRHAGIA ON FOLLOW UP

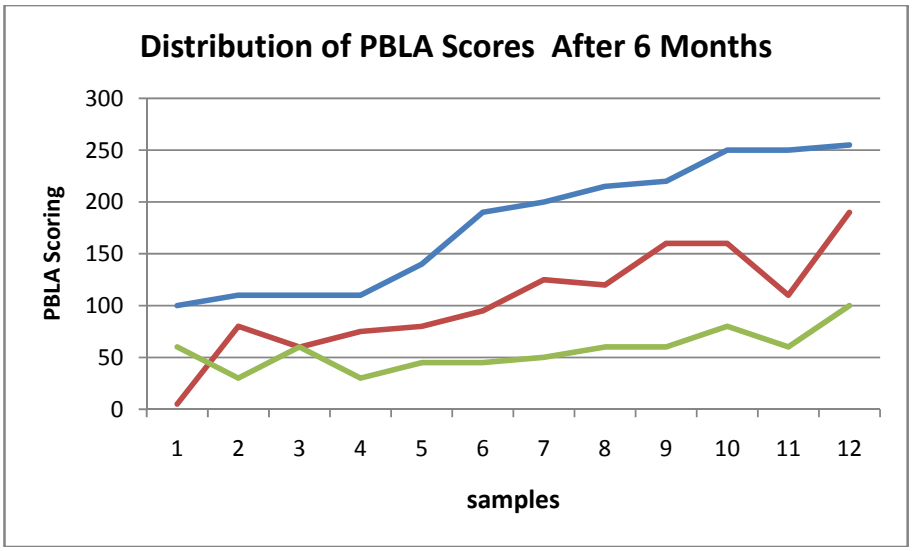
At 3 months menstrual blood loss was significantly reduced. 83% had moderate to significant improvement in their mean blood loss. Pictoral blood loss scoring reduction ranges from 10 to 95% at the 3rd month and 45 to 76% at the 6th month. By paired‘t’ test reduction in blood loss at 3 months was highly significant with $p<0.00001$.

Table: 13. Distribution of Improvement In Blood Loss After 3 Months

Improvement In The Blood Loss	No. of Subjects	%
Worsening < 0	0	0
Remaining The Same 0-10%	0	0
Mild-10-30%	05	16.67
Moderate-30-50%	16	53.33
Good >=50%	09	30.00
Total Subjects	30	100.00



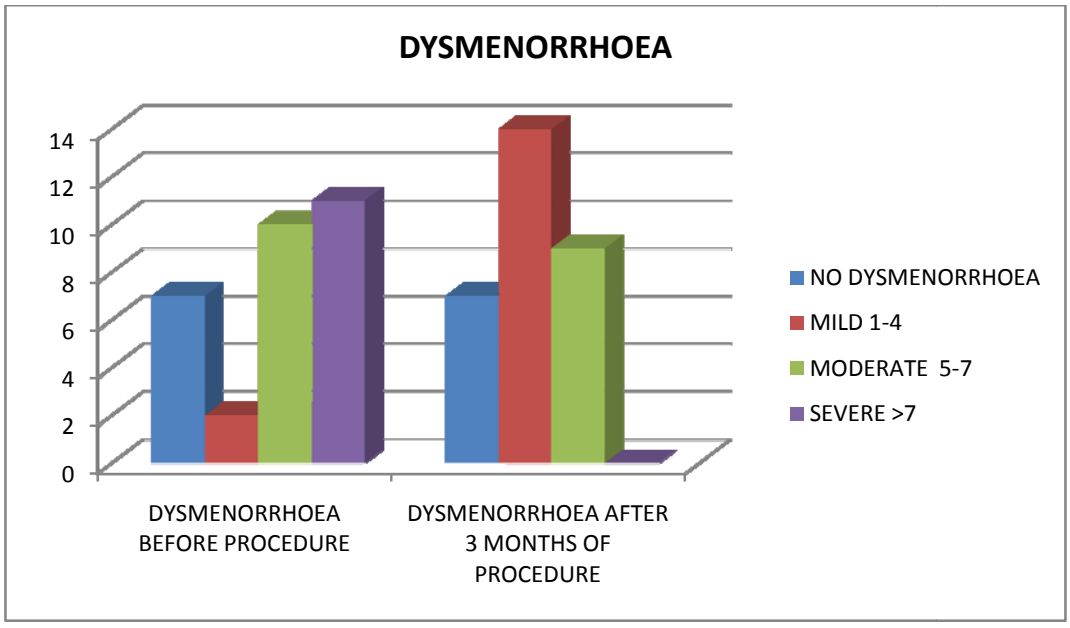
At 6 months menorrhagia markedly reduced. All the patient had PBLA scoring of <100 that is no menorrhagia after 6 months.



DYSMENORRHOEA ON FOLLOW UP:

Among 23 patients presented with dysmenorrhoea significant improvement in dysmenorrhea seen in 87% of patients. Only 2 of the patient's dysmenorrhea remained the same at 3 months. At the end of 6 months none of the patients had severe dysmenorrhoea.

Table: 14. Improvement In Dysmenorrhoea After 3 Months		
	Before Procedure	After 3 Months
Nil	7	7
Mild (1-4)	2	14
Moderate (5-7)	10	9
Severe (>7)	11	0
	30	30



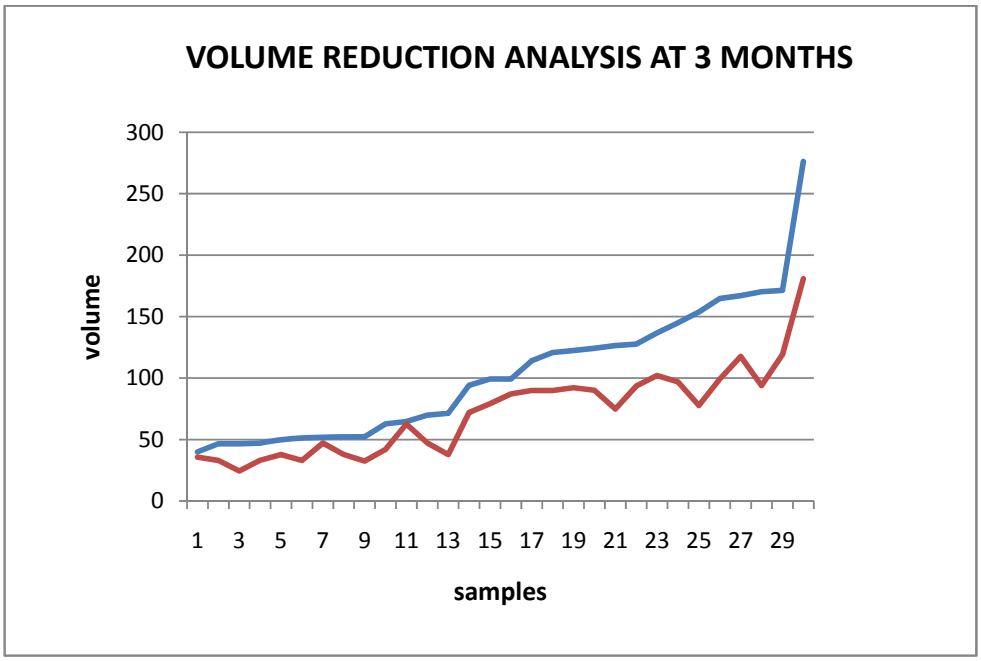
VOLUME CHANGES:

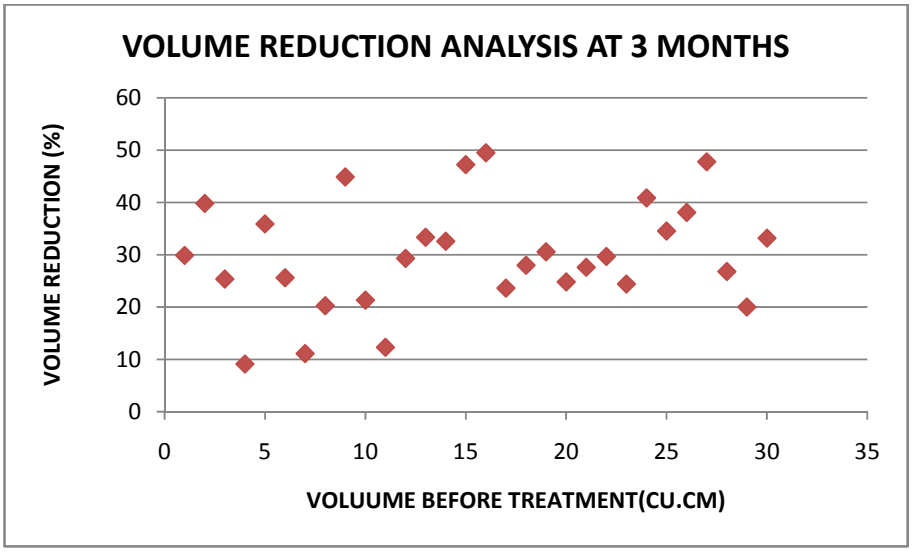
Uterine fibroid embolisation acts mainly by occluding the blood supply to the tumour thus it arrests the growth and causes ischemia and necrosis of the tumour. This causes shrinkage of the tumour and prevents grow of new fibroids as per long term follow up studies.

In this study, mean reduction in the volume at the 3rd month was 29.91% and at the 6th month was 46.66%. Range of volume reduction varied from 9 to 50% at 3 months and 27-65% at 6 months. Paired "t" test was used to analyse the volume change after 3 months. It was highly significant with p value of <0.0001 at 3 months.

Table:15. Volume Reduction of Fibroid After 3 Months

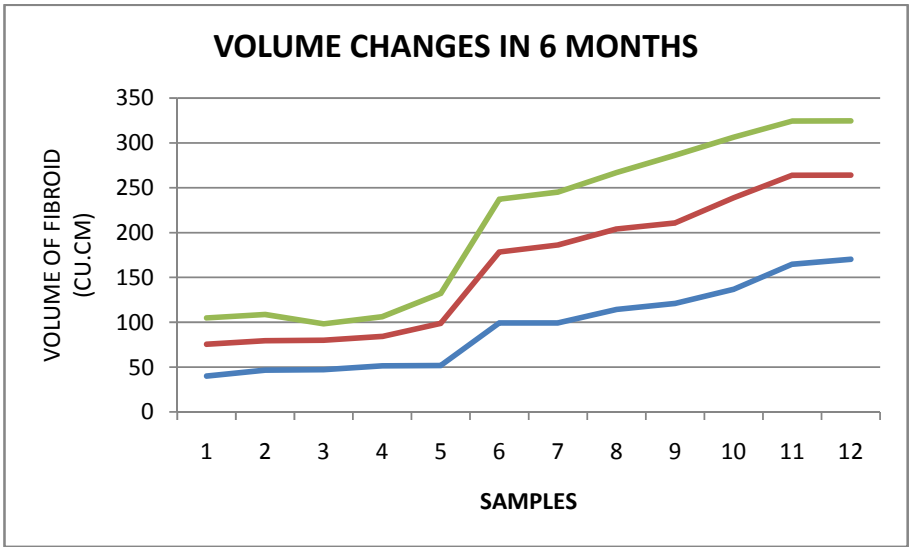
	No. Of Subjects	%
Worsening	0	0
Remaining The Same 0-10	01	03.33
Mild-10-30	17	56.67
Moderate-30-50	12	40.00
Total Subjects	30	100.00





In this study moderate to marked reduction in dominant fibroid volume was seen in 40% of the patients at 3rd month and 91% at 6th month.

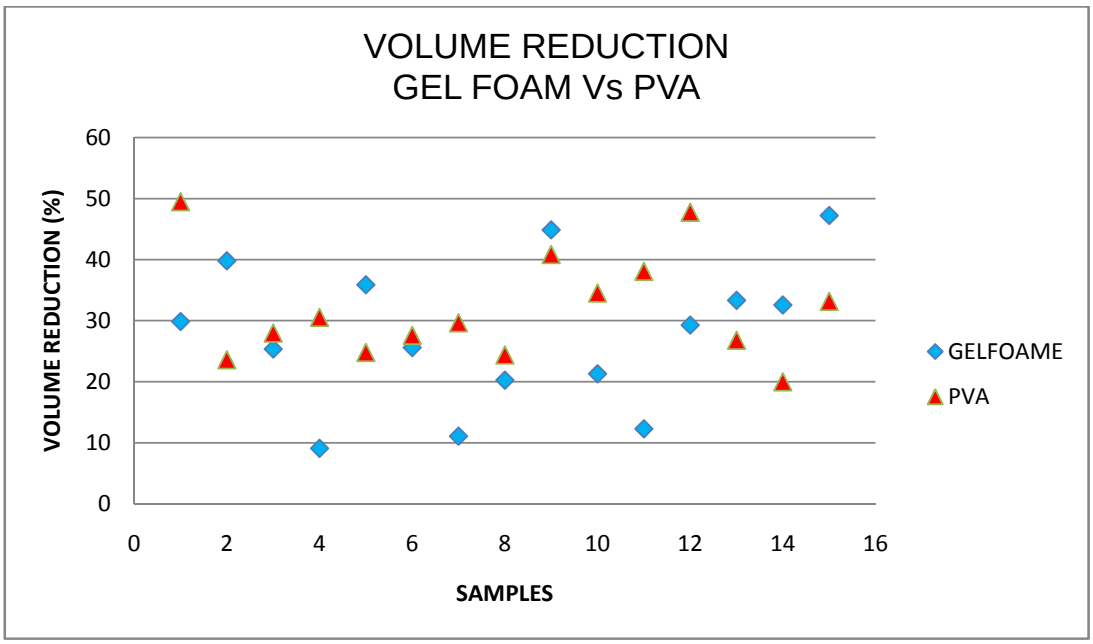
Table: 16. Reduction In Fibroid Volume After 6 Months		
	No. Of Subjects	%
Worsening	0	0
Remaining The Same 0-10	0	0
Mild-10-30	1	08.33
Moderate-30-50	6	50.00
Good >=50	5	41.67
Total Subjects	12	100.00



VOLUME REDUCTION GELFOAM Vs PVA:

For embolisation we have used gel foam for 15 patients and poly vinyl alcohol for 15 patients. On analysing the volume reduction at 3 months, mean volume reduction for gel foam and poly vinyl alcohol was 27.86% and 31.95% respectively. **By unpaired t test value p value was** 1.15 (>0.5) which was **insignificant**.

TABLE:17 VOLUME REDUCTION GELFOAM VS PVA				
	VOLUME	%REDUCTION	VOLUME	%REDUCTION
1	47.07	29.8	69.82	49.5
2	164.75	39.8	71.38	23.6
3	136.66	25.3	153.76	28.0
4	51.78	9.1	94.14	30.5
5	51.4	35.8	52.3	24.8
6	120.81	25.6	171.33	27.6
7	40	11.1	122.38	29.7
8	99.23	20.2	124.26	24.4
9	170.23	44.9	167.04	40.9
10	114.22	21.3	49.81	34.5
11	99.23	12.3	126.46	38.1
12	46.6	29.2	276.14	47.8
13	62.76	33.3	52.3	26.8
14	64.72	32.6	46.6	19.9
15	144.97	47.2	127.71	33.2
AVERAGE	94.29	27.86	113.7	31.9
RANGE(%)		11.1-44.9		23.6-49.5



PRESSURE SYMPTOMS:

In this study 6 of them had pressure symptoms. 4 had increased frequency of micturation. 2 had lower abdominal heaviness. Pressure symptoms disappeared at 3 months for all of them.

Table:18" Pressure Symptoms After Treatment"

Pressure symptoms	Before treatment	3 months after treatment
Frequency of micturation	04	0
Lower abdominal heaviness	02	0
Total	6	nil

No long term complication seen in this study.

CONSOLIDATION OF RESULTS				
Age	Mean	32.43yrs	Range	26-39yrs
Mean volume of fibroid	104 cu cm	Range	40.01- 276.14 cu cm	
Presenting complaints			**No. of samples**	**%**
Menorrhagia			30	100.00
Dysmenorrhoea			23	76.66
Pressure Symptom	Frequency of micturation		04	13.33
	Lower abdominal heaviness		02	06.67
Technical difficulties				
Unilateral embolisation	Vasospasm		1	3.12
	Subintimal dissection		1	3.12
Unsuccessful catheterisation	Vasospasm		2	6.25
Bilateral embolisation			28	87.5
Mean Duration of procedure		65min	Range	45to 75 min.
Mean duration of hospital stay		2.6 days	Range	2-7 days
Follow up analysis	**Improvement after 3 mths**	**Improvement after 6 mths**	**P value**	**Inference**
Menorrhagia	83%	100%	*P<0.00001*	Highly significant
Dysmenorrhoea	87%	100%	*P<0.00001*	Highly significant
Volume changes	29.91%	46.66%	*P <0.0001*	Highly significant
Mean volume reduction Gel foam vs PVA	**Gel foam**	27.86%	*P = 1.15*	Not significant
	PVA	31.95%		

IMAGES

PELVIC ANGIOGRAM

FIG 8.1: CONTRALATERAL PELVIC ANGIOGRAM

FIG 8.2: IPSILATERAL PELVIC ANGIOGRAM

FIG 8.3: SELECTIVE ANGIOGRAM OF UTERINE ARTERIES

FIG 8.4: ARTERIAL PHASE OF CONTRAST

FIG 8.5: VENOUS PHASE OF CONTRAST

FIG 8.6: POST EMBOLISATION STANDING COLLUM OF CONTRAST

FIG 8.7: PRE EMBOLISATION – ULTRASONOGRAPHY

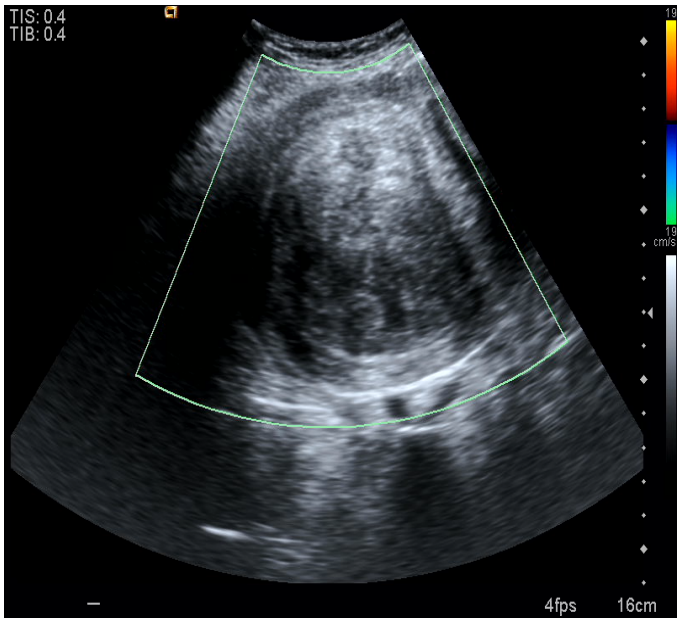


FIG 8.8: PRE EMBOLISATION - 2D COLOR DOPPLER

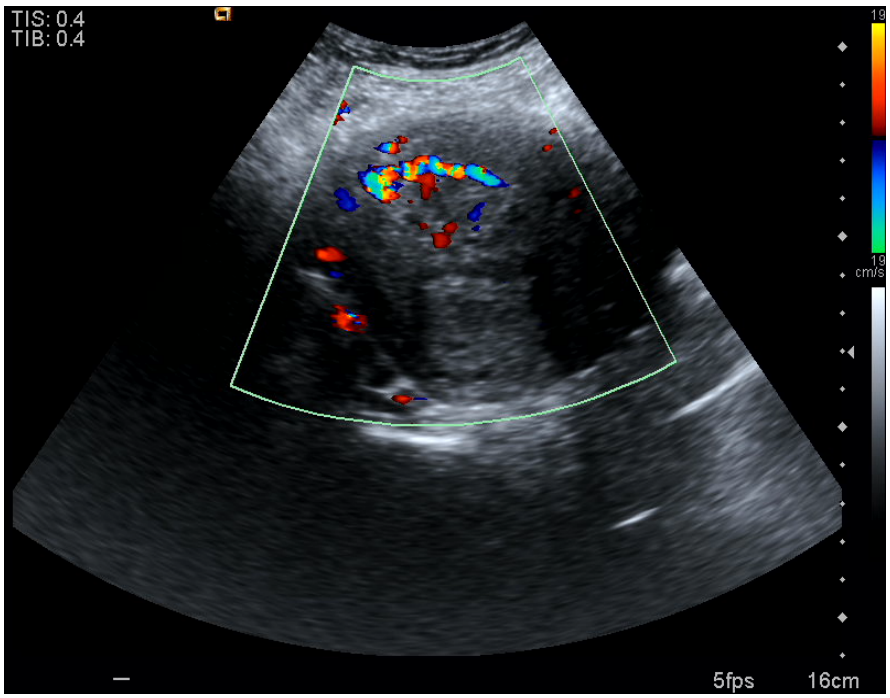


FIG 8.9: POST EMBOLISATION ULTRASONOGRAPHY

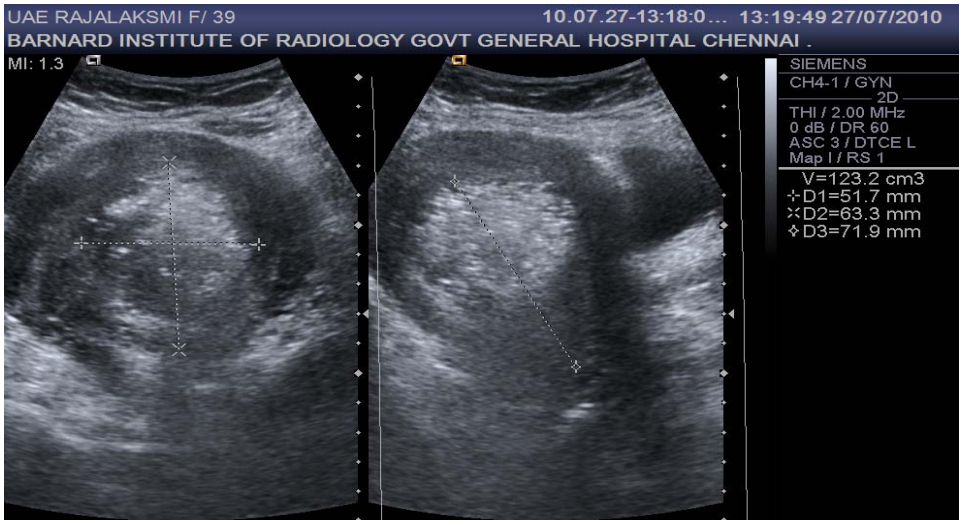


FIG 8.10: POST EMBOLISATION 3D COLOR DOPPLER

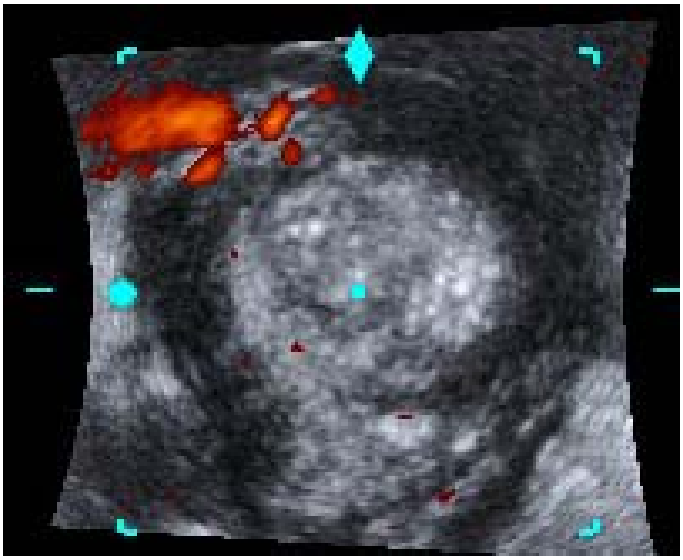


FIG 8.11 :EMBOLISATION IN A PATIENT WITH PELVIC KIDNEY

FIG 8.12: SELECTIVE ANGIOGRAM OF UTERINE ARTERIES

FIG 8.13: EMBOLISATION OF LEFT SIDE UTERINE ARTERY

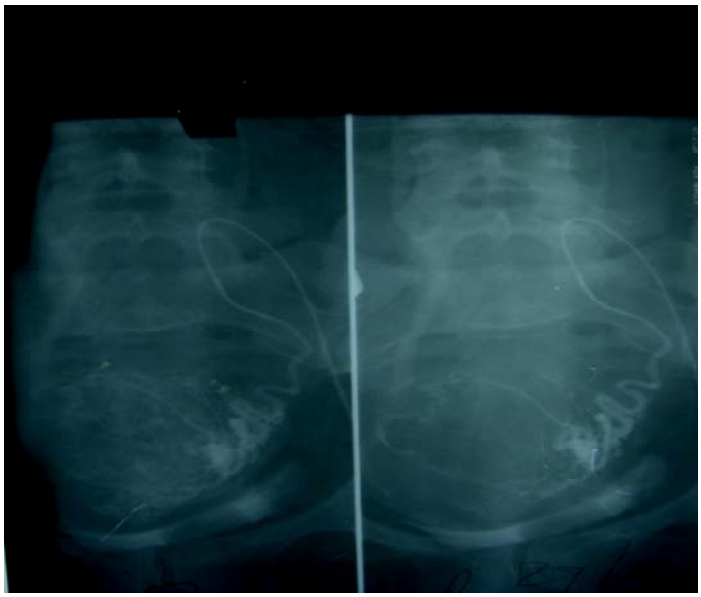


FIG 8.14: POST EMBOLISATION- COLLUM OF CONTRAST

DISCUSSION

DISCUSSION

Fibroid uterus is one of the common benign gynaecological disorders encountered in the reproductive age group. Although various medical treatments available they are ineffective because of their side effects and temporary relief. Hence many young women forced to undergo hysterectomy at an early age. Uterine artery embolisation is minimally invasive alternative primary treatment of fibroids with preservation of uterus. This study was done to know the effectiveness, tolerability and complication of this procedure which can be used as primary procedure.

Samples were collected according to the inclusion and exclusion criteria. They were assessed in detail and contra-indications were ruled out. Totally 32 samples were taken for the study. For 2 patients embolisation could not be done because of vasospasm. **Successful embolisation** was done for 30 patients. Hence we have analysed data for 30 patients.

Indication for UFE: Out of 30, 23(76.67%) of them preferred UFE to hysterectomy. In the remaining samples, 5 (16.67) had severe anaemia, one had under gone previous surgery and one was morbidly obese thus preferred UAE to prevent surgical and other complications.

Majority of the patients opted to undergo Uterine Artery Embolisation because of the following benefits:

- Short duration of hospital stay.
- Simple procedure.
- Safe compared to hysterectomy as per previous studies
- Satisfactory results of the previous studies.
- Avoid surgical complications (Anaemic patients, obese patients and patients undergone previous surgery – anaesthetic risk, infection and injury to vital structure because of adhesion)

Mean **Age** of the study population was 32.43 years which ranges from 26-39. The study population below 40 years were selected because, as age increases associated problems like carcinoma of endometrium and ovarian pathologies increases which mandates surgical management. Above the age of 40 years 3% of myomas are associated with endometrial carcinoma[45]. Also in post menopausal women and perimenopausal women the fibroid size regresses after menopause because of its estrogens dependent nature.

Menorrhagia was present in all the patients which were assessed by Pictoral Blood Loss Assessment Chart. As per **Higham et al**[43] who analysed pictoral blood loss, PBAC scoring of >100 is diagnostic of menorrhagia, that is blood loss of >80ml with specificity and sensitivity of >80%. All patient in this study had Pictoral blood loss assessment scoring of >100. Average blood loss scoring in this study was 202.66 and ranges from 100-315.

Dysmenorrhoea was present in 23(76.66%) of the subjects and was assessed by Visual Analogue Scale[42]. Before embolisation mild dysmenorrhoea was present in 2(7%) patients, moderate dysmenorrhoea was present in 10(33.3%) patients and severe dysmenorrhoea in 11(37%) patients.

In this study **Pressure Symptoms** was present in only 6(20%) of the selected population. This may be because of the restriction of size of fibroid <7c.m.4 (13.33%) had increased frequency of micturation and 2(6.67%) had feeling of lower abdominal heaviness.

In this study, average **volume of fibroid** before embolisation is 104 cu.cm. Largest fibroid in the study population was 10x 8x6.2 cm & volume 274.14 cu.cm. Previously said large fibroids are associated with more complication. In our series we have not encountered any additional complications in larger fibroids. This correlates with the recent study by **Albret J Smeetsetal** [23] shows complications were not increased and clinical response is also good.

In this study **unilateral femoral puncture technique** was used in all patients. Bilateral femoral puncture with cross-over technique which was used initially for UAE was faster and needs shorter screening time than unilateral catheterization. However, with experience, ipsi-lateral catheterization of uterine artery can be carried out quickly and is widely practiced today. We have used unilateral femoral puncture technique, not encountered any complication related to femoral puncture and catheterisation.This correlated with the study, **Pelage**

JP, Soyer P, et al. [35], found unilateral femoral puncture was safe and with lesser incidence of complications such as haematoma and dissection of arteries.

Pre procedural antibiotics and analgesics were given to all patients. None of the patients required any further sedatives or anaesthesia during the procedure.

Successful bilateral embolisation was done for 28 (87.5%) of the patients. **Technical difficulties** was seen in 4 (12.5%) of the patients. Catheterisation of uterine artery could not be done because of vasospasm. Unilateral embolisation was done in two patient and other two patients catheterisation could not be done on both sides and the procedure abandoned. This is comparable with **Brunereau et al.**[46] Who reported 84% successful catheterisation. **Pelage et al**[35]. reported successful catheterisation in 92% of cases.

Serious complication rates in this study were 3.33% which is little higher compared to other studies. This can be attributed to smaller sample size. We have encountered one sub intimal dissection alone and no other serious complications like vascular perforation or allergy to contrast media noted. **Spice et al** [37] who published the largest series found an overall 8.5% short-term complication rate and a 1.25% serious complication rate. Infective complications have been noted in other studies which were not seen in this study. **Vashisht et al**.[47] reported one death due to septicaemia following UAE leading to multiorgan failure. **Walker and Pelage**[48] have reported three (1%)

infective complications leading to hysterectomy. Hence, pre-existing infection must be excluded and proper antibiotic cover must be given before UAE. Expulsion of fibroids vaginally after UAE has been reported in 2.5% of patients by **Goodwin et al**.[24] and Walker and Pelage[48]. In this study, no such incidence was recorded.

Duration of the procedure varied from 45 minutes to 75 minutes. The average duration of the procedure was 65 minutes. This is comparable with results of previous researches. The mean total procedure time as reported by other investigators has been 78.4 min for bilateral approach[18] and 44.29[49] and 61[44] min for unilateral approach. **Fluoroscopic exposure time** was 45 min, which is more compared with reported times of 25.3[18], 13.69[49] and 18.9[44] min. In this study intermittent fluoroscopy was used to reduce the exposure.

Post Procedural Events: Majority of the patients (90%) complained of pain in the lower abdominal and low back ache. Pain subsided with NSAIDs. Rarely narcotic analgesics needed. 20% had vomiting and 10% had fever. All these complications were self limiting. Patients observed for 48 hours 72 hours and then discharged. None of the patients developed hematoma or any other serious complication in immediate post procedure period. One patient had post embolisation syndrome (PES) and was re-admitted after a week.

Patients were advised to take bed rest for 6 hrs, then minimal activity upto 24hrs, after that were ambulated well and observed in hospital. Patients without complications were discharged on the 2nd or 3rd day.

Mean **Duration of Hospitalisation** was 2.6 days in this study. Most of the patients were discharged on 2nd or 3rd day. Only one patient who had sub-intimal dissection was discharged on 7th day. She was treated with heparin 5000u sc BD. MRI Scan and Doppler flow was assessed and found to be normal. Another patient was readmitted with the complaints of fever and myalgia. She was treated with antibiotics & antipyretics and was investigated for infections which were negative. Patient recovered after 2 days and was discharged. Pain and vomiting was seen in most of the patients. Pain was confined to lower abdomen and back region and was reduced with NSAIDS. Duration of hospital stay is comparable with **Brunereau L, et al.**[46] who reported 2.3 days. In some hospitals the patients discharged after an over night stay. This can also suggested in future, as there was no complication seen after 24 hrs.

Follow up: Patients are called at the end of 3 months and 6 months. Menorrhagia was assessed by Pictoral Blood Loss Assessment Chart and dysmenorrhea by Visual analogue Scale.USG was done to know the size of fibroid.

In this study on the 3rd month follow up, there was significant **Improvement in Menorrhagia** (83% of patients) (*p<0.00001 highly significant)*. No patients had worsening of menorrhagia. At 6 months all (100%) patients had PBLA scoring below 100 that is blood loss <80 ml. It was comparable to the study reported by **Ravina et al**[12] (81%) and **Goodwin et al.**[28] (81%). Improvement in blood loss ranges from 10 to 95 % at 3 months. At the 6th month the improvement in menorrhagia ranges from 45 to 76%.One (3.33%) patient had **Transient Amenorrhoea**. She resumed her menstruation 4 months after the procedure. No cases of permanent amenorrhoea seen in this study.

Similarly there was significant **Improvement in Dysmenorrhea** seen in 87% of patients. Only 2 of the patient's dysmenorrhea remained the same at 3 months. At the end of 6th month none of the patients had severe dysmenorrhea. This results correlated with the findings of **Mahmood et al.**[17] from Stansford University who showed 74% had improvement in dysmenorrhea.

Average **Volume Reduction** at the 3rd month was 29.91 % (*p<0.0001 highly significant)* and 6th month was 44.66%. Range of volume reduction varied from 9 to 50% at 3 months and 27-65% at 6 months. It comparable with that seen in the study by **Spies et al.**[18], who has reported 50% at 6th month and 78% at 1st year.

Gelfoam Vs Poly Vinyl Alcohol as embolic agent: Among 30 patients in the study 15 of them were embolised with gel foam and remaining 15 was embolised with ploy vinyl alcohol particles of 350-500 µm size. On analysing the volume reduction, both was equally effective. This result is comparable with **Katz et al**[36] who studied the effectiveness of gelatin sponge pledgets versus polyvinyl alcohol for embolization. They concluded that materials are equally effective.

CONCLUSION

CONCLUSION

From this study we have found that Uterine Artery Embolisation for the patients having symptomatic uterine fibroid is an effective and safe alternate treatment with significant reduction in patient's symptoms and good patient's satisfaction. It has less failure rates in short term follow up. Although long term follow needed to confirm it. Single femoral puncture technique can be used to embolise both uterine arteries successfully in most of the patients. Both the embolizing agents (Gel foam & PVA) are equally effective in relieving the symptoms. This procedure has good patient's tolerance, short recovery time, quick and sustained symptomatic improvement. As the previous studies do not support future fertility it should be used with caution in patients who want future conception. Careful selection of cases and proper counselling before embolisation can bring maximum success to the procedure. This procedure may reduce the need for invasive surgery in many patients. From this study we conclude that UFE is a minimally invasive, safe and effective treatment for properly selected patients with uterine fibroids.

LIMITATIONS OF THE STUDY:

- Smaller sample size.
- It is a short term follow up.

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PERFORMA

Name:

Indication for UFE: opted / anaemia / previous surgeries / obesity / others

Age (yrs): 25-30 31-35 35-40

History:

- Menorrhagia - Assessed by Pictoral Blood Loss Assessment Chart
- Dysmenorrhoea – Assessed by Visual Analogue Scale
- Pressure Symptoms: Yes/no
- Increased frequency and urgency: Yes/no
- Lower abdominal heaviness: Yes/no
- Constipation: Yes/no
- Marital status: married/unmarried
- Obstetric history: No of children Nil / 1 / 2 / >2
- History of Allergy: Yes/no
- History of previous surgeries: Yes / No

Clinical Examination:

- General Examination:
  - Height : Weight: BMI:

- Anaemia:
- Peripheral edema:
- Miscellaneous:

- CVS:
- RS:
- Abdomen:
- Gynaecological Examination:
- Speculum examination:
- P/V:

Investigations

- Hb%:
- Blood sugar :
- Urea: S creatinine:
- TC : DC: ESR:
- HIV:
- HbsAg:
- BT: CT:

Fractional Curettage Report:

PAP smear:

USG:

- Mean Uterine sizes:
- No. of fibroids:
- Size of fibroids:
- Largest axis of largest fibroid:
- Volume of fibroid:
- Calcification / degeneration:

Doppler:

- hypovascular / hypervascular

Uterine Artery Embolisation:

Done on:

Duration of procedure:

Catheterisation: unilateral/bilateral

Embolisation: No / unilateral / bilateral

Embolic particle used: Gel foam/PVA

Complication During procedure:

- Vasospasm :Yes/No
- Vascular-perforation :Yes/No
- Subintimal-dissection :Yes/No

- Allergy :Yes/No
- Mis-embolisation :Yes/No
- Miscellaneous.

Immediate post procedure complications

- Pain :Yes/No
- Vomiting :Yes/No
- Post embolic syndrome :Yes/No
- Deep vein thrombosis :Yes/No

Late complication

- Vaginal discharge :Yes/No
- Fever :Yes/No
- Trans cervical expulsion :Yes/No
- Amenorrhoea :Yes/No

Patient discharged on:

Follow up at 3months:

- Menstrual blood loss:
- Dysmenorrhea:
- Pressure symptom:
- Fibroid size by USG:

Follow up at 6months:

- Menstrual blood loss:
- Dysmenorrhea:
- Pressure symptom:
- Fibroid size by USG: Volume:

Key to master chart

M- Menorrhagia

D-dysmenorrhea

P-pressure symptoms

F-Frequency of micturation

H-Lower abdominal heaviness

PBLA Scoring - Pictorial Blood Loss Assessment Scoring

VAS - Visual Analogue Scale

SID-Subintimal dissection

VS-Vasospasm

Fe- Fever

Vo-Vomiting

Pa-Pain

PES-Post embolisation syndrome

GF-Gel Foam

PVA-Poly Vinyl Alcohol

0- Unsuccessful catheterisation

1-Unilateral embolisation

2-Bilateral embolisation

ABBREVATIONS

UAE - Uterine Fibroid Embolization

UFE - Uterine Fibroid Embolization

PBLA Scoring - Pictorial Blood Loss Assessment Scoring

VAS - Visual Analogue Scale

USG - Ultrasound

PES - PostEmbolisation Syndrome

AVMs - Arterio Venous Malformations

HRQOL - Health Related Quality Of Lifea